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**(Final version)**

## **Covid-19 vaccines: ethical, legal and practical considerations**

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## A. Draft Resolution

1. The pandemic of Covid-19, an infectious disease caused by the novel coronavirus SARS-CoV-2, has caused much suffering in 2020. By December, more than 65 million cases had been recorded worldwide and more than 1.5 million lives had been lost. The disease burden of the pandemic itself, as well as the public health measures required to combat it, have devastated the global economy, laying bare pre-existing fault-lines and inequalities (including in access to health care), and causing unemployment, economic decline and poverty.
2. Rapid deployment worldwide of safe and efficient vaccines against Covid-19 will be essential in order to contain the pandemic, protect health-care systems, save lives and help restore global economies. Although non-pharmaceutical interventions such as physical distancing, the use of facemasks, frequent hand washing, as well as shutdowns and lockdowns, have helped slow down the spread of the virus, infection rates are now rising again across most of the globe. Many Council of Europe member States are experiencing a second wave which is worse than the first, while their populations are increasingly experiencing “pandemic fatigue” and are feeling demotivated about following recommended behaviours to protect themselves and others from the virus.
3. Even rapidly deployed, safe and effective vaccines, however, are not an immediate panacea. Following the festive season at the end of the year 2020 and the beginning of 2021, with its traditional indoor gatherings, infection rates will likely be very high in most member States. In addition, a correlation has just been scientifically established by French doctors between outdoor temperatures and the disease incidence rate on hospitalisations and deaths. The vaccines will no doubt not be sufficient to bring down infection rates significantly this winter – in particular when taking into account that demand far outstrips supply at this point. A semblance of “normal life” will thus not be able to resume even in the best of circumstances until mid to late 2021 at the earliest.
4. For the vaccines to be effective, their successful deployment and sufficient uptake will be crucial. However, the speed at which the vaccines are being developed may pose a difficult to combat challenge to building up trust in them. An equitable deployment of Covid-19 vaccines is also needed to ensure the efficacy of the vaccine. If not widely enough distributed in a severely hit area of a country, vaccines become ineffective at stemming the tide of the pandemic. Furthermore, the virus knows no borders and it is therefore in every country's interest to co-operate on ensuring global equity in access to Covid-19 vaccines. Vaccine hesitancy and vaccine nationalism have the capacity to derail the so-far surprisingly fast and successful Covid-19 vaccine effort, by allowing the SARS-CoV-2 virus to mutate and thus blunt the world's most effective instrument against the pandemic so far.
5. International co-operation is thus needed now more than ever in order to speed up the development, manufacturing

and fair and equitable distribution of Covid-19 vaccines. The Covid-19 Vaccine Allocation Plan, also known as COVAX, is the leading initiative for global vaccine allocation. Co-led by the World Health Organization (WHO), the Vaccine Alliance (Gavi) and the Coalition for Epidemic Preparedness Innovations (CEPI), the initiative pulls funding from subscribing countries to support the research, development and manufacturing of a wide range of Covid-19 vaccines and negotiate their pricing. Adequate vaccine management and supply chain logistics, which require international co-operation and preparations by member States, will also be needed in order to deliver the vaccines against the virus in a safe and equitable way. In this regard, the Parliamentary Assembly draws attention to guidance for countries on programme preparedness, implementation and country-level decision-making developed by WHO.

6. Member States must already now prepare their immunisation strategies to allocate doses in an ethical and equitable way, including deciding on which population groups to prioritise in the initial stages when supply is short, and how to expand vaccination as availability of one or more Covid-19 vaccines improves. Bioethicists and economists largely agree that persons over 65 years old and persons under 65 with underlying health conditions putting them at a higher risk of severe illness and death, health-care workers (especially those who work closely with persons who are in high-risk groups), and people who work in essential critical infrastructure should be given priority vaccination access. Children, pregnant women and nursing mothers, for whom no vaccine has so far been authorised, should not be forgotten.

7. Scientists have done a remarkable job in record time. It is now for governments to act. The Assembly supports the vision of the Secretary General of the United Nations that a Covid-19 vaccine must be a global public good. Immunisation must be available to everyone, everywhere. The Assembly thus urges member States and the European Union to:

- 7.1. with respect to the development of Covid-19 vaccines:

- 7.1.1. ensure high quality trials that are sound and conducted in an ethical manner in accordance with the relevant provisions of the Convention on human rights and biomedicine (ETS No. 164, Oviedo Convention) and its Additional Protocol concerning Biomedical Research (CETS No. 195), and which progressively include children, pregnant women and nursing mothers;
- 7.1.2. ensure that regulatory bodies in charge of assessing and authorising vaccines against Covid-19 are independent and protected from political pressure;
- 7.1.3. ensure that relevant minimum standards of safety, efficacy and quality of vaccines are upheld;

#### **Amendment 4**

**Tabled by Mr Aleksandr BASHKIN, Ms Vera GANZIA, Mr Leonid KALASHNIKOV, Mr Sergey KISLYAK, Mr Maksim KUDRIAVTSEV, Mr Yury OLEINIKOV, Ms Irina RODNINA, Mr Roman ROMANENKO, Ms Irina RUKAVISHNIKOVA, Mr Shamsail SARALIEV**

*In the draft resolution, at the end of paragraph 6, insert the following sentences:*

*"When taking such decisions we must take into account those categories of individuals who already possess antibodies to Covid-19 and are thus not needing primarily the vaccination, which leads to reducing the burden on vaccine industry and immunisation centres. In this context, where appropriate, we should aim first to examine a patient in order to detect before vaccination a possible presence of Covid-19 antibodies."*

- 7.1.4. implement effective systems for monitoring the vaccines and their safety following their roll-out to the general population, also with a view to monitoring their long-term effects;
- 7.1.5. put in place independent vaccine compensation programmes to ensure compensation for undue damage and harm resulting from vaccination;
- 7.1.6. pay special attention to possible insider trading by pharmaceutical executives, or pharmaceutical companies unduly enriching themselves at public expense, by implementing the recommendations contained in Resolution 2071 (2015) on Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?

#### **Amendment 3**

**Tabled by Mr Georgios KATROUGKALOS, Mr Andrej HUNKO, Mr Tiny KOX, Mr Hisyar ÖZSOY, Mr Sokratis FAMELLOS, Ms Nina KASIMATI, Mr Alexandros TRIANTAFYLIDIS**

*In the draft resolution, after paragraph 7.1.6, insert the following paragraph:*

*"overcome the barriers and restrictions arising from patents and intellectual property rights, in order to ensure the widespread production and distribution of vaccines in all countries and to all citizens."*

- 7.2. With respect to the allocation of Covid-19 vaccines:
  - 7.2.1. ensure respect for the principle of equitable access to health care as laid down in Article 3 of the Oviedo Convention in national vaccine allocation plans, guaranteeing that Covid-19 vaccines are available to the population regardless of gender, race, religion, legal or socio-economic status, ability to pay, location and other factors that often contribute to inequities within the population;
  - 7.2.2. develop strategies for the equitable distribution of Covid-19 vaccines within member States, taking into account that the supply will initially be low, and prepare for how to expand vaccination programmes when the supply expands; follow the advice of independent national, European and international bioethics committees and institutions, as well as of WHO, in the development of these strategies;
  - 7.2.3. ensure that persons within the same priority groups are treated equally, with special attention to the most vulnerable people such as older persons, those with underlying conditions and health care workers, especially those who work closely with persons who are in high-risk groups, as well as people who work in essential infrastructure and in public services, in particular in social services, public transport, law enforcement, and schools, as well as those who work in retail;
  - 7.2.4. promote equity in access to Covid-19 vaccines between countries by supporting international efforts such as the Access to Covid-19 Tools Accelerator (ACT Accelerator) and its COVAX Facility;
  - 7.2.5. refrain from stockpiling Covid-19 vaccines which undermines the ability of other countries to procure vaccines for their populations, ensure stockpiling does not translate to escalating prices for vaccines from those who stockpile to those who cannot, conduct auditing and due

#### **Amendment 2**

**Tabled by Mr Stefan SCHENNACH, Ms Edite ESTRELA, Mr Jean-Pierre GRIN, Mr Vladimir**

diligence to ensure rapid deployment of vaccines at minimum cost based on need not market power;

**KRUGLYI, Baroness Doreen MASSEY, Ms Sibel ARSLAN**

*In the draft resolution, after paragraph 7.2.5, insert the following paragraph:*

*“ensure that every country is able to vaccinate their health-care workers and vulnerable groups before vaccination is rolled out to non-risk groups, and thus consider donating vaccine doses or accept that priority be given to countries which have not yet been able to do so, bearing in mind that a fair and equitable global allocation of vaccine doses is the most efficient way of beating the pandemic and reducing the associated socio-economic burdens;”*

7.2.6. ensure that Covid-19 vaccines whose safety and effectiveness has been established are accessible to all who require them in the future, by having recourse, where necessary, to mandatory licences in return for the payment of royalties;

7.3. With respect to ensuring high vaccine uptake:

7.3.1. ensure that citizens are informed that the vaccination is NOT mandatory and that no one is politically, socially, or otherwise pressured to get themselves vaccinated, if they do not wish to do so themselves;

7.3.2. ensure that no one is discriminated against for not having been vaccinated, due to possible health risks or not wanting to be vaccinated;

7.3.3. take early effective measures to counter misinformation, disinformation and hesitancy regarding Covid-19 vaccines;

7.3.4. distribute transparent information on the safety and possible side effects of vaccines, working with and regulating social media platforms to prevent the spread of misinformation;

7.3.5. communicate transparently the contents of contracts with vaccine producers and make them publicly available for parliamentary and public scrutiny;

7.3.6. collaborate with non-governmental organisations and/or other local efforts to reach out to marginalised groups;

7.3.7. engage with local communities in developing and implementing tailored strategies to support vaccine uptake.

7.4. With respect to Covid-19 vaccination for children:

7.4.1. ensure balance between the rapid development of vaccination for children and duly addressing safety and efficacy concerns and ensuring complete safety and efficacy of all vaccines made available to children, with a focus on the best interest of the child, in accordance with the United Nations Convention on the Rights of the Child;

7.4.2. ensure high quality trials, with due care for relevant safeguards, in accordance with international legal

- standards and guidance, including a fair distribution of the benefits and risks in the children who are studied;
- 7.4.3. ensure that the wishes of children are duly taken into account, in accordance with their age and maturity; where a child's consent cannot be given, ensure that agreement is provided in other forms and that it is based on reliable and age appropriate information;
  - 7.4.4. support UNICEF in its efforts to deliver vaccines from manufacturers that have agreements with the COVAX Facility to those who need them most;
  - 7.5. With respect to ensuring the monitoring of the long-term effects of the COVID-19 vaccines and their safety:
    - 7.5.1. ensure international co-operation for timely detection and elucidation of any safety signals by means of real-time global data exchange on adverse events following immunisation (AEFIs);
    - 7.5.2. eliminate any gaps in communication between local, regional and international public health authorities handling AEFI data and overcome weaknesses in existing health data networks;
    - 7.5.3. bring pharmacovigilance closer to health-care systems;
    - 7.5.4. support the emerging field of adversomics research which studies inter-individual variations in vaccine responses based on differences in innate immunity, microbiomes and immunogenetics.
  8. With reference to Resolution 2337 (2020) on Democracies facing the Covid-19 pandemic, the Assembly reaffirms that, as cornerstone institutions of democracy, parliaments must continue to play their triple role of representation, legislation and oversight in pandemic circumstances. The Assembly thus calls on parliaments to exercise these powers, as appropriate, also in respect of the development, allocation and distribution of Covid-19 vaccines.

#### **Amendment 1**

**Tabled by Mr Stefan SCHENNACH, Mr Jean-Pierre GRIN, Mr Vladimir KRUGLYI, Baroness Doreen MASSEY, Ms Selin SAYEK BÖKE, Ms Martine WONNER, Ms Sibel ARSLAN**

*In the draft resolution, after paragraph 7.5.1, insert the following paragraph:*

*“use vaccination certificates only for their designated purpose of monitoring vaccine efficacy, potential side-effects and adverse events;”*